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(54) Vein needle set

(57) An injection needle set for transfusion or injection of blood etc. comprises a flexible injection tube 12 and an inserted metal needle 9, the needle being connected to a cylindrical rod 5 moveable within a cylinder 3 so as to be withdrawable from said injection tube, and a flexible shield 20 of bacterially impervious material such as polyethylene which surrounds said cylindrical rod as it is itself withdrawn from said cylinder 3 to thereby withdraw the needle. The shield is attached at one end to the cylinder 3 and at its other end to a portion 2 of the rod 5 which connects to a transfusion tube 4 or the like, and prevents bacterial contamination of the needle set during use.

FIG 3.

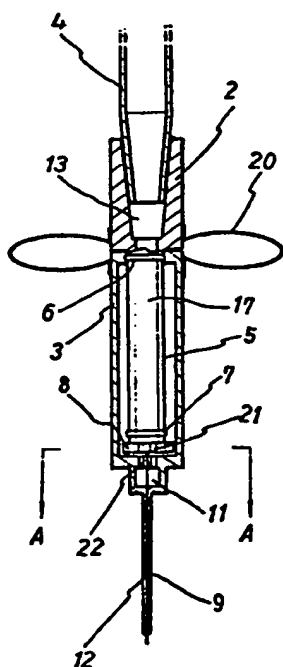
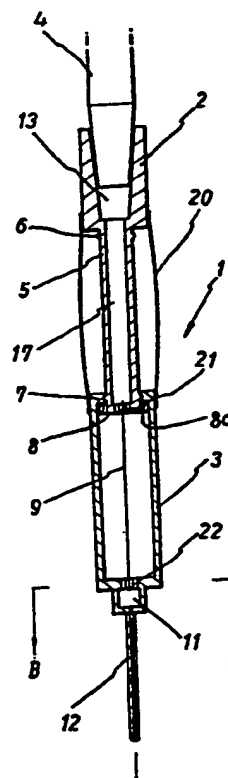


FIG 4.



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FIG. 1.

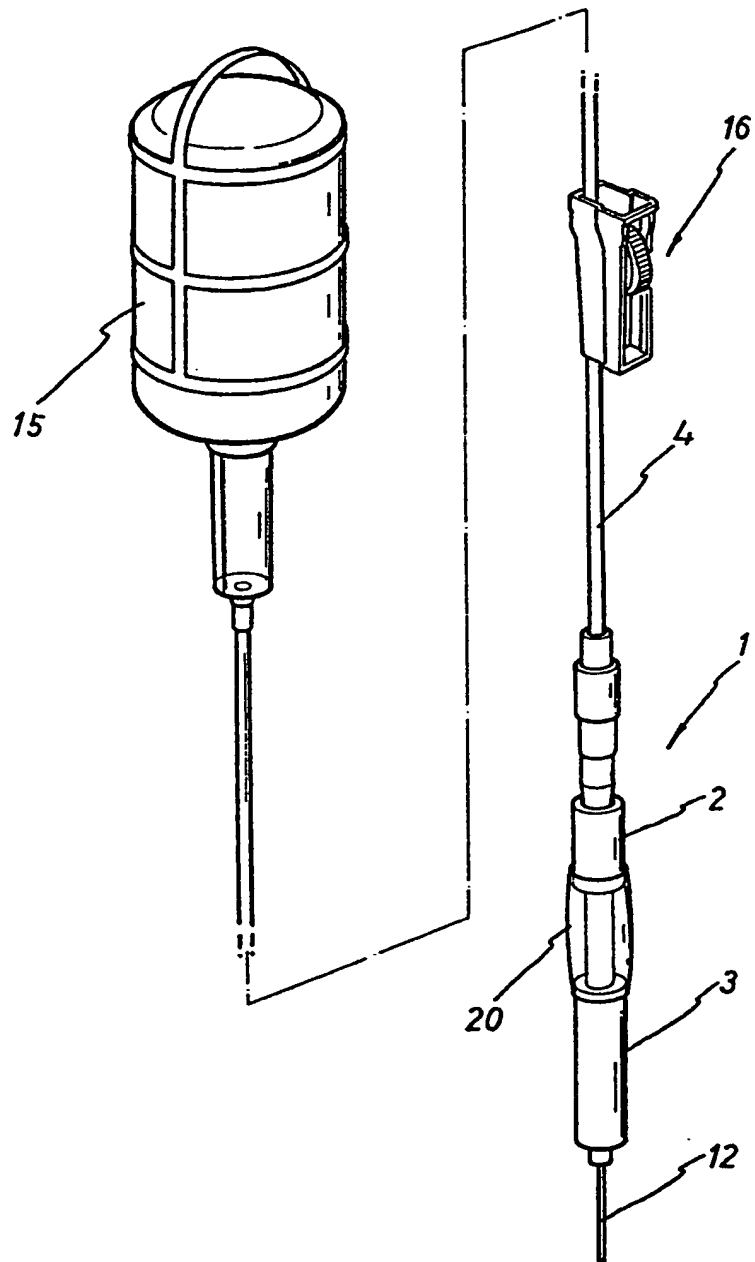


FIG 2.

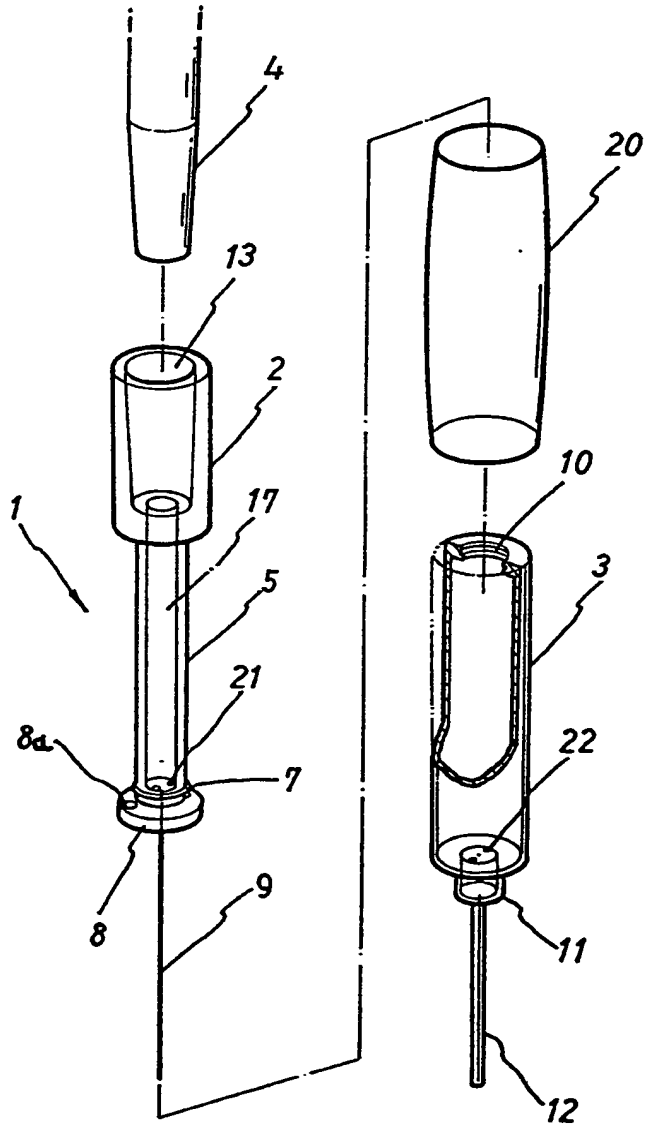


FIG 3.

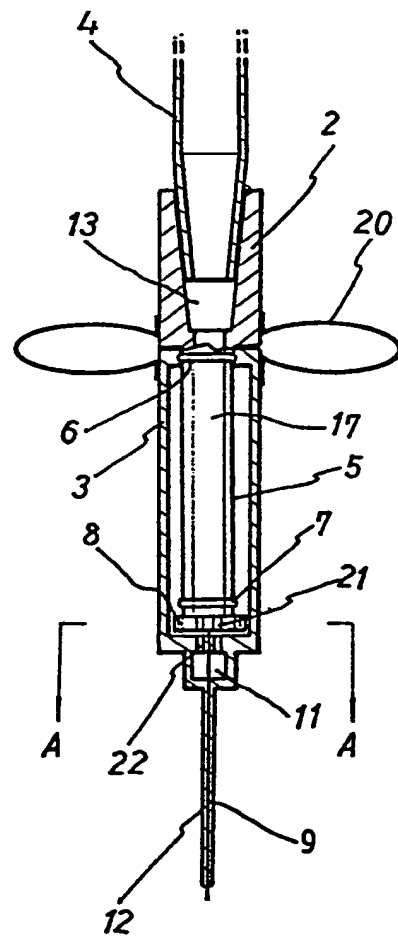


FIG 4.

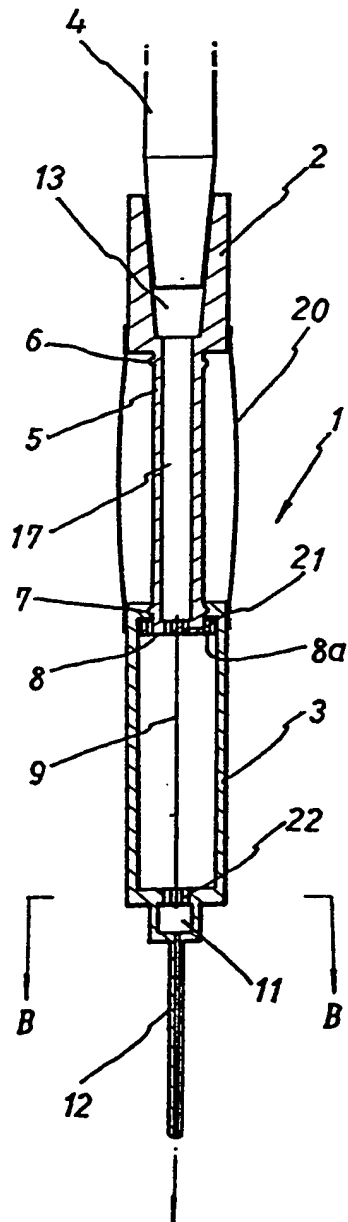


FIG 5.

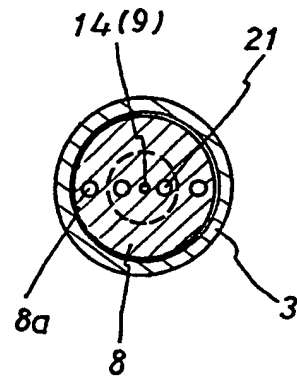
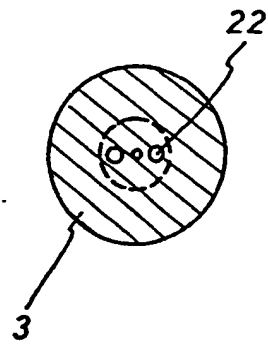


FIG 6.



VEIN NEEDLE SET

Background of the Invention

Field of the Invention

With regard to the so called "one time use" polytetrafluoroethylene (hereinafter "PTFE") injection needle sets, the device of the present invention is aimed at smoothing the transfusion of blood (or other injected biological fluid) while simultaneously cutting off intrusion of bacteria into the cylindrical rod of the device, in the course of the transfusion, by sealing the cylindrical rod and the cylinder of the device with a thin polyethylene shield.

The PTFE vein needle sets in use are made of a metal needle, which metal needle is pricked through the skin and into the blood vessel with the metal needle being removed after the PTFE tube is in place in the blood vessel. PTFE vein injection needles in use so far are used in the following manner:

- 1) the PTFE vein injection tube is pricked through the skin and into the blood vessel by using a metal needle and thereafter the metal needle is removed;
- 2) a transfusion tube of either a blood transfusion set, an injection set or an injector is connected to the upper portion of the stopper of the device; and
- 3) the transfusion of blood or injection is made by the injector.

Since the injection is made by the use of a metal needle, and the needle is to be removed immediately after the injector is connected to the blood or injection transfusion tube or to the injector, the device of the prior art has the deficiencies of:

- 1) leaking of blood or injected fluid during the connection and injection;

2) connection not only takes much time and requires skilled technicians, but also requires an additional replacement PTFE tube when the injection tube under injection in one blood vessel is moved to another location since the metal needle is removed.

Especially, to inject into another blood vessel, the original PTFE tube has to be replaced by a new one after the blood or injection transfusion tube is disconnected and the metal needle must be immediately removed after a replacement needle is pricked into the blood vessel and the tube must be connected to the injector. Therefore, these processes cause a grave deficiency by allowing bacterial infection.

#### Objects and Summary of the Invention

For that very reason, the device of the present invention is designed to eliminate the aforementioned deficiencies, and the details of the device are as follows:

1) The disclosed device, a PTFE vein needle set, can be used either as an original set or by reinserting the metal needle into the flexible tube, and simply by moving the metal needle to an upper position after the metal needle and the PTFE tube are punctured in the blood vessel, transfusion of blood, injection or injection in the injector can be made immediately without any leaking, and time for preparing and injection can be saved;

2) Especially, an injection into another blood vessel can easily be made by only repositioning the metal needle into the PTFE tube, without replacing the PTFE tube, with a new one. The disclosed invention has as one of its principal objects, the prevention of bacterial infection in the course of injection by utilizing the aforementioned device in the disclosed manner.

Also, the disclosed invention has, for a principal aim, the provision of a one time use PTFE vein injection tube set that makes speedy and smooth transfusion of blood or injection possible, and is also aimed at keeping the needle set free from bacteria infection, by sealing the cylindrical rod of the device from exposure to the atmosphere when injection is taking place with a thin biologically impervious shield.

#### Brief Description of the Drawings

Fig. 1 is a schematic perspective figure of this device showing its overall connections; wherein

A transfusion tube 4 is connected from the bottom of a source of blood or other biological fluid contained in an injection container 15 to the top of the PTFE needle assembly, and the flow regulator 16 is installed between the two points;

Figs. 2, 3 and 4 show schematic perspective, sectional and functional drawings of disassembled device.

Fig. 5 is a sectional view along A-A of Fig. 3; and

Fig. 6 is a sectional view along B-B of Fig. 4.

#### Detailed Description of the Invention

The disclosed device is composed of the following components and has, as its function, the achievement of the aforementioned aims and objects.

The improved one time use PTFE injection needle set of the invention is generally illustrated at 1 in Fig. 1. The set 1 includes a cylinder 3, through which a cylindrical rod 5 is relatively moveable.

The round plate 8 installed at the lower end of cylindrical rod 5 in cylinder 3 moves up and down together with cylindrical



rod 5 by moving the connector 2. The distance through which cylindrical rod 5 is moveable is limited within the cylinder 3 by upper protrusions 6 and lower protrusions 7 (Fig. 4). A transfusion tube 4 is connected to the connecting groove 13 of the connector 2 and to the metal needle 9 -PTFE tube 12 combination through the rod hole 17 in the cylindrical rod 5. The cylinder 3 is furnished with a concave groove 10 on its upper portion and with a cavity compartment 11 underneath the cylinder.

The up-and-down movement of the connector 2, cylindrical rod 5 and the metal needle 9, connected to the bottom of the cylindrical rod 5, permits easy injections from one blood vessel to another without replacing the PTFE vein injection needle set while the transfusion of blood or injection is proceeding.

An elastic transparent plastic, such as a polyethylene shield 20, is provided which is sealed to the lower part of the connector 2 and to the upper part of the cylinder 3, and keeps the cylindrical rod 5 isolated from bacterial infection and atmosphere external to the set 1.

The passage hole 17 above the cavity compartment 11, the hole 8a on the round plate 8 and the passage hole 22 at the lower end of the cylinder 3 are assembled in aligned condition.

In addition to the aforementioned description of the device, the detailed description of the components of the device and their function will be further understood from a description of the method of use of the set 1.

In use, a transfusion tube 4 is inserted into connecting groove 13 of the connector 2, with the protrusions 6 and 7 at the top and bottom, respectively, of the cylindrical rod 5 limiting the up-and-down length of movement of the cylindrical rod 5 within cylinder 3. Hole 8a on the round plate 8 at the bottom of

cylindrical rod 5 is aligned into fluid communication with the PTFE tube 12 with the metal needle 7 tightly piercing through the PTFE tube 12. The top of the metal needle 9 protrudes approximately 1mm at the tip of the tube 12 at the time of injection to be made.

The polyethylene shield 20 is sealed between the upper portion of the cylinder 3 and the lower portion of the connector 2 to keep the cylindrical rod 5 isolated from the atmosphere thereby preventing intrusion of bacteria. The shield 20 is preferably made of a bacterially impermeable material, such as a transparent elastic polyethylene material, so that the polyethylene shield 20 is both flexible when cylindrical rod 5 is moving and permits visible inspection of the device enclosed by polyethylene shield 20.

As shown on the Figs. 5 and 6, a passage 21 in the round plate 8 and the passage hole 22 are furnished in alignment so as to make smooth flow of blood or other injected fluid from the rod hole 17 to the cavity compartment 11.

The disclosed device is so designed so as to be used in the following manner, and has the following attendant advantages.

By making the metal needle tip 9 protrude about 1mm at the end of the PTFE tube 12 after the transfusion tube 4 is connected to the connecting groove 13 of the connector 2, and pricking of the metal needle 9 through the skin and into the blood vessel of an animal or human patient, the cylinder 3 is held with one hand and the connector 2 is pulled upward with the other hand to cause the device to assume the shape as illustrated in Fig. 4. Then a source of injectable fluid, such as the contents of container 15 flows into the blood vessel through the transfusion tube 4, the flow of which is regulated by flow regulator 16, through

connecting groove 13, rod hole 17, metal needle 9, cavity compartment 11, PTFE tube 12 and finally into the blood vessel of the patient. The thinner the PTFE tube 12 is the better, as it has some flexible tension so as not to injure the blood vessel of the patient receiving the injection even upon movement of the PTFE tube 12. The metal needle 9, having an aperture or vertical hole 14 therein, is capable of moving up and down tightly inside the PTFE tube 12. As shown in Figs. 3 and 4, the flexible polyethylene shield 20 is sealed to the upper part of the cylinder 3 and to the lower part of the connector 2 to protect the cylindrical rod 5 from contamination with the environment thereby preventing a patient from being infected by bacteria.

The upper protrusion 6 at the top of cylindrical rod 5 maintains proper connection between connector 2 and cylinder 3 while the lower protrusion 7 also maintains proper connection to the concave groove 10 at the point where the connector 2 is pulled upward to its maximum height, and restricts the distance of movement of the connector 2 accordingly. At this point (shown in Fig. 4), the tip of the metal needle 9 is located at the top of the cavity compartment 11, and makes the transfusion of blood or injection easier, but maintains close contact with the upper part of the cavity compartment 11 so as not to make the reverse flow of the blood or injection in the cavity compartment 11 into the cylinder 3 while the transfusion process is under way.

Since the transfusion of the blood or the injection made solely through the metal needle 9 is not sufficient in its volume and/or slow in its flow speed, the transfusion can also be made through the passage 21 at the bottom of the rod hole 17, so that a portion of the blood (or other injection fluid) is caused to flow through the cylinder 3, and through the cavity compartment

11 after passing through the passage hole 22. After the blood (or other injection fluid) flows to the compartment 11, then the transfusion is easily made directly to the blood vessel through the PTFE tube 12.

In the event it is necessary to relocate the PTFE needle assembly set 1 from one blood vessel to another location on the same patient, the PTFE tube 12 is removed from its location on the blood vessel after the connector 2 is returned from its extended portion shown in Fig. 4 to the original position shown in Fig. 3, then injection with the metal needle tip 9 protruded about 1mm out from the tip of the PTFE tube 12 can proceed in another vein or in another location on the same patient when the upper protrusion 6 is fit into the concave groove 10.

The hole 8a on the round plate 8 keeps the air pressure inside the cylinder 3 stable with that of the external atmosphere. It is preferable for the tip of the metal needle 9 to be very sharp and the connector 2 should have proper tension to prevent leakage.

Since there is a frequent need to move cylindrical rod 5 to relocate the PTFE tube 12 when relocating the transfusion device from one blood vessel to another location, the polyethylene shield protects the cylindrical rod 5 from being infected by bacteria from the external surroundings.

The disclosed device, can therefore make the transfusion relocation in a simple and speedy manner with the transfusion tube 4 and the injector needle set 1 connected, without any leaking or wasting of the needle by following the simple procedures previously mentioned. Also, the disclosed device can make a bacteria-free transfusion of blood (or other injection fluid) from one blood vessel to another, accordingly, by sealing

the cylindrical rod 5 that has to be moved during the process, it provides for the smooth and stable transfusion effect to the maximum extent by means of the rod hole 17, passage 21 and passage holes 22 and the cavity compartment 11.

Furthermore, this device requires no replacing of the transfusion tube 4 or the injection needle set 1 while the transfusion is in process, can make the transfusion easier by following the simple processes herein disclosed and provides a bacterial infection-free transfusion.

Variations may be made in procedures for use, substitutions of various materials and proportions without departing from the scope of the invention as defined by the following claims.

CLAIMS

1. An injection needle set for the transfusion or injection of blood or other biological fluids, said set comprising:

a metal injection needle;

a flexible injection tube;

a cavity compartment in fluid communication with said flexible injection tube;

a cylinder in fluid communication with said cavity compartment, said cylinder having a cylindrical rod therein;

said cylindrical rod being moveable in said cylinder from a point proximate said cavity compartment to a point remote from said cavity compartment and a connector for connecting said set to a source of blood or other biological fluids;

said metal injection needle being connected to said cylindrical rod so as to be moveable with said rod and a bacterially impervious shield attached to said connector and to said cylinder so as to surround said rod during movement thereof.

2. An injection needle set as claimed in claim 1, wherein the shield is made from an elastic plastics material.

3. An injection needle as claimed in claim 1 or claim 2, wherein the shield is a flexible transparent polyethylene shield.

4. An injection needle set as claimed in any one of the preceding claims, wherein the cylindrical rod includes a hole therein permitting fluid flow therethrough.

5. An injection needle set as claimed in any one of the

preceding claims, wherein the cylindrical rod includes a round plate attached to its end proximate the cavity compartment.

6. An injection needle set as claimed in claim 5, wherein the round plate has passageways therethrough.

7. An injection needle set as claimed in any one of the preceding claims, wherein the arrangement is such that the metal needle protrudes from the distal end of the flexible injection tube when the rod is located proximate to said cavity compartment.

8. An injection needle set as claimed in claim 7, wherein the metal needle protrudes about 1mm past the end of the flexible injection tube.

9. An injection needle set as claimed in any one of the preceding claims, wherein the flexible injection tube is formed of polytetrafluoroethylene.

10. An injection needle set as claimed in any one of the preceding claims, in which the cylindrical rod is provided with an upper and/or a lower engagement means for limiting its movement.

11. An injection needle set as claimed in claim 10, wherein the cylinder is provided with corresponding engagement means at its end remote from said cavity compartment.

12. An injection needle set for medical use comprising an injection tube connected in fluid communication with a housing comprising one or more communicating chambers that, in turn, communicate with connecting means for attachment to supply or collection apparatus, a needle connected, in th

housing, to reciprocating means and moveable into and out of the injection tube by operation of the reciprocating means, and shield means so arranged as to prevent bacterial infection during the said movement.

13. An injection needle set, substantially as hereinbefore described with reference to, and as illustrated by, Figs. 1 to 6 of the accompanying drawings.

14. A method of operating an injection needle set as claimed in any one of claims 1 to 13, comprising the steps of:

- (a) inserting the needle in the injection tube and placing in a desired location;
- (b) withdrawing the needle from the tube while maintaining the injection tube in the desired location;
- (c) preventing bacterial infection by means of the shield means; and
- (d) connecting the needle set by means of the connecting means to supply or collection apparatus.

15. A method of transfusing or injecting blood or other biological fluid into the vein of an animal or human patient, said method comprising the steps of:

- (a) inserting a metal needle into the vein of a patient;
- (b) withdrawing the metal needle from said vein while maintaining a flexible tube in said vein;
- (c) preventing said withdrawn metal needle from contamination by surrounding the metal needle with a bacterial impervious shield;
- (d) connecting said flexible tube in fluid communication



with a source of blood or other biological fluid.

16. A method as claimed in claim 15, further including the steps of reins rting the metal needle into said flexible tube in said vein; withdrawing both said metal needle and flexible tube from said vein; and reinserting the metal needle into another location on the same patient.

17. An method as claimed in claim 16, wherein said other location is another vein.

18. A method as claimed in any one of claims 14 to 17, wherein the needle is withdrawn by moving a cylindrical rod in a cylinder where the needle is connected to the cylindrical rod.

19. A method as claimed in any one of claims 14 to 18, wherein said shield means extends during withdrawal of the needle.

20. A method as claimed in any one of claims 14 to 19, wherein said shield means contracts during reinsertion of the needle into the tube.

21. A method as claimed in any one of claims 14 to 20, wherein the needle is caused to protrude about 1mm beyond the edge of the tube when reinserted into the tube.

22. Any novel feature hereinbefore described or any novel combination of hereinbefore described features.